Remarks

Claims 1, 10, 15, 21, 24-28, 32, and 39-68 were pending in the subject application. By this Amendment, claim 43 has been amended; new claims 69-81 have been added. The undersigned avers that no new matter is introduced by this amendment and submits that support for the amended claims may be found, for example, in the as filed specification at page 11, lines 33-36, page 46, lines 21-29, and page 44, lines 1-16 and the originally presented claims. Accordingly, claims 1, 10, 15, 21, 24-28, 32, and 39-81 are currently before the Examiner for consideration. Entry and favorable consideration of the pending claims is respectfully requested.

It is noted that the Office Action indicates that an election to prosecute Group I (drawn to claims 38 and newly presented claims 43-68) was made by John Lucas on August 21, 2001. Applicants note, however, that Group III was elected in the Response filed on August 22, 2001 in this matter and that this Office Action indicates that claims 43-68 form inventive group III. Accordingly, Applicants affirm the election of Group III in this matter. Applicants also respectfully request that any requirement to cancel claims not currently under examination be held in abeyance in order to allow for the rejoinder of claims directed to methods of making and/or using the compositions claimed herein in light of Patent Office policy related to the treatment of product and process claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b) at such time as the composition claims currently pending are found allowable

Claims 43-68 have been rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the invention was made, had possession of the claimed invention. The Office Action asserts that the specification fails to contain a sufficient disclosure of the structure and function of all GGPPSASE fragments or portions of SEQ ID NO:4. The Office Action further asserts that the genus of polypeptides within this genus is large and variable with the potentiality of encoding many different proteins and that the description of polypeptides comprising 10, 20, 50, or 100 amino acids of SEQ ID NO:4 is insufficient to describe the structure of the polypeptides of the claims. The Office Action has also rejected claims 43-68 under 35 U.S.C. §112, first paragraph, because the specification, while enabling for the GGPPSASE of SEQ ID NO:4, does not reasonably provide enablement for fragments of SEQ ID NO:4 of unknown structure and function. Particularly, the Office Action asserts that the specification does not enable the person

skilled in the art to make the invention commensurate in scope with the claims. The Office Action indicates that undue experimentation would be required on the part of one skilled in the art in order to practice the invention as claimed. Applicants respectfully traverse.

Applicants respectfully submit that the specification, as filed, provides an adequate written description of the polypeptides claimed herein and that no undue experimentation is required on the part of the skilled artisan in view of the teachings of the specification. The claimed composition comprises an isolated recombinant polypeptide comprising a contiguous span of at least 6 amino acids of SEQ ID NO:4, wherein the contiguous span is a truncated polypeptide sequence of the hGGPPS protein sequence (SEQ ID NO:4) and wherein said contiguous span includes at least one amino acid selected from the group consisting of: a.) a Phe residue at position 204 of SEQ ID NO:4; b.) a Phe residue at position 295 of SEQ ID NO:4; c.) a Cys residue at position 205 of SEQ ID NO:4; and d.) a Pro residue at position 225 of SEQ ID NO:4. As such, one skilled in the relevant art would have recognized that the claimed recombinant polypeptide comprises a contiguous span of at least six amino acids that have the polypeptide sequence of SEQ ID NO:4 and is shorter than the full length sequence of SEQ ID NO:4.

Applicants also respectfully submit that the skilled artisan would, in view of the teachings of the specification, be apprised of the structure and function of the polypeptide composition claimed herein. For example, the specification teaches that truncated polypeptides of the invention have a polypeptide sequence comprising at least 6 amino acids of SEQ ID NO:4 and include at least one amino acid selected from the group consisting of Phe at positions 204, 257, 295, Cys at position 205, Pro at position 225, and Glu at position 252 of SEQ ID NO:4 (see specification, page 44, lines 1-16). Additionally, one skilled in the art would have recognized, at the time the application was filed, that isolated recombinant polypeptides of the subject invention comprising truncated polypeptides of SEQ ID NO:4 of at least six amino acids would have various biological activities, including but not limited to, GGPPS activity, the ability to specifically bind to antibodies that also bind to full length hGGPPS, or the ability to specifically bind to antibodies that specifically recognize a contiguous span of at least six amino acids of SEQ ID NO:4 (see page 47, lines 2-3, 10-22, or 26-31). Accordingly, it is respectfully submitted that the specification, as filed, apprised the skilled man as to the structure and function of the claimed polypeptide function; reconsideration and withdrawal of the rejection is respectfully requested.

It is also respectfully submitted that undue experimentation would not be required to practice the presently claimed invention. The present claims are drawn to compositions comprising an isolated recombinant polypeptide comprising a contiguous span of at least 6 amino acids of SEQ ID NO:4, wherein the contiguous span is a truncated polypeptide sequence of the hGGPPS protein sequence (SEQ ID NO:4) and wherein said contiguous span includes at least one amino acid selected from the group consisting of: a.) a Phe residue at position 204 of SEQ ID NO:4; b.) a Phe residue at position 295 of SEQ ID NO:4; c.) a Cys residue at position 205 of SEQ ID NO:4; and d.) a Pro residue at position 225 of SEQ ID NO:4. As indicated supra, the claimed polypeptides can have any of a variety of functional attribute, including, but not limited to, enzymatic activity or the ability to specifically bind to antibody molecules. Additionally, the claims indicate that the contiguous span of amino acids in the claimed polypeptide are a truncated polypeptide of the hGGPPS polypeptide of SEQ ID NO:4. It is respectfully submitted that undue experimentation would not be required on the part of the skilled artisan to identify those polypeptides (that comprise a contiguous span of at least six amino acids and wherein the contiguous span was a truncated polypeptide sequence of SEQ ID NO:4) that had either enzymatic activity or the ability to specifically bind antibodies, such as those taught in the subject application. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 43-68 have been rejected under 35 U.S.C. §102(e) as being anticipated by Greene et al. (U.S. Patent No. 5,786,193) or under 35 U.S.C. § 102(b) as being anticipated by Greene et al. (WO 96/21736). The Office Action indicates that the references teach a composition comprising a polypeptide that is 100% identical to that of the claimed invention. Applicants respectfully traverse.

The claimed invention is directed to a composition comprising an isolated recombinant polypeptide comprising a contiguous span of at least 6 amino acids of SEQ ID NO:4, wherein the contiguous span is a truncated polypeptide sequence of the hGGPPS protein sequence (SEQ ID NO:4) and wherein said contiguous span includes at least one amino acid selected from the group consisting of: a.) a Phe residue at position 204 of SEQ ID NO:4; b.) a Phe residue at position 295 of SEQ ID NO:4; c.) a Cys residue at position 205 of SEQ ID NO:4; and d.) a Pro residue at position 225 of SEQ ID NO:4. It is respectfully submitted that the prior art references fail to teach such a composition. For example, the references are silent with respect to recombinant polypeptides that comprise a contiguous span of at least 6 amino acids of SEQ ID NO:4, wherein the contiguous span

is a truncated polypeptide sequence of the hGGPPS protein sequence (SEQ ID NO:4) and wherein said contiguous span includes at least one amino acid selected from the group consisting of: a.) a Phe residue at position 204 of SEQ ID NO:4; b.) a Phe residue at position 295 of SEQ ID NO:4; c.) a Cys residue at position 205 of SEQ ID NO:4; and d.) a Pro residue at position 225 of SEQ ID NO:4. While Applicants note that the prior art rejections are based upon the teaching of the full length sequence of the polypeptide of Figure 3, it is respectfully submitted that the reference is devoid of any teachings of truncated forms of that polypeptide. For example, it is noted that the references refer to, and claim, fragments of the polypeptides of Figure 1 (SEQ ID NO:2) or polypeptides encoded by the deposited clone ATCC 75900. Applicants submit that the polypeptide sequence of SEQ ID NO:2 fails to teach contiguous span of at least 6 amino acids of SEQ ID NO:4, wherein the contiguous span is a truncated polypeptide sequence of the hGGPPS protein sequence (SEQ ID NO:4) and wherein said contiguous span includes at least one amino acid selected from the group consisting of: a.) a Phe residue at position 204 of SEQ ID NO:4; b.) a Phe residue at position 295 of SEQ ID NO:4; c.) a Cys residue at position 205 of SEQ ID NO:4; and d.) a Pro residue at position 225 of SEQ ID NO:4. Particularly, SEQ ID NO:2 does not teach Phe residues at positions 204 and 295, a Cys residue at position 205, or a Pro residue at position 225. Accordingly, it is respectfully submitted that the subject invention is not anticipated by the cited prior art; reconsideration and withdrawal of the rejection is respectfully requested.

It is also respectfully submitted that the prior art references also fail to render the claimed invention obvious under 35 U.S.C. § 103(a). In determining whether a case of prima facie obviousness exists, it is necessary to ascertain whether the prior art teachings would appear to be sufficient to one of ordinary skill in the art to suggest making the claimed substitution or other modification. *In re Taborsky*, 502 F.2d 775, 780, 183 U.S.P.Q. 50, 55 (C.C.P.A. 1974). In other words, the Patent Office must establish why one skilled in the art would have been motivated to provide a compositions comprising a an isolated recombinant polypeptide comprising a contiguous span of at least 6 amino acids of SEQ ID NO:4, wherein the contiguous span is a truncated polypeptide sequence of the hGGPPS protein sequence (SEQ ID NO:4) and wherein said contiguous span includes at least one amino acid selected from the group consisting of: a.) a Phe residue at position 204 of SEQ ID NO:4; b.) a Phe residue at position 295 of SEQ ID NO:4; c.) a Cys residue at position 205 of SEQ ID NO:4; and d.) a Pro residue at position 225 of SEQ ID NO:4.

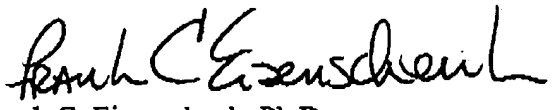
Further, to establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art (*In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974)) and the fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a prima facie case of obviousness (*In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994)). It is also respectfully submitted that, in order to establish a case of *prima facie* obviousness, it is incumbent upon the Patent Office to determine whether one of ordinary skill in the relevant art would have been motivated to make the claimed invention as a whole, *i.e.*, to select the claimed species or subgenus from the disclosed prior art genus. *See, e.g.*, *In re Ochiai*, 71 F.3d 1565, 1569-70, 37 USPQ2d 1127, 1131 (Fed. Cir. 1995); *In re Deuel*, 51 F.3d 1552, 1557, 34 USPQ2d 1210, 1214 (Fed. Cir. 1995)(A prima facie case of unpatentability requires that the teachings of the prior art suggest the claimed compounds to a person of ordinary skill in the art); *In re Jones*, 958 F.2d 347, 351, 21 USPQ2d 1941, 1943-44 (Fed. Cir. 1992; *In re Dillon*, 919 F.2d 688, 692, 16 USPQ2d 1897, 1901 (Fed. Cir. 1991); *In re Lalu*, 747 F.2d 703, 705, 223 U.S.P.Q. 1257, 1258 (Fed. Cir. 1984) (The prior art must provide one of ordinary skill in the art the motivation to make the proposed molecular modifications needed to arrive at the claimed compound.). *See also In re Kemps*, 97 F.3d 1427, 1430, 40 USPQ2d 1309, 1311 (Fed. Cir. 1996) (discussing motivation to combine).

In view of the foregoing remarks and amendments to the claims, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 or 1.17 as required by this paper to Deposit Account 19-0065.

The applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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Attachment: Marked-Up Version of Claims

Marker-Up Version of Claims

Claim 43. (Currently Amended)

A composition comprising an isolated recombinant polypeptide comprising a contiguous span of at least 6 amino acids of SEQ ID NO:4, wherein the contiguous span is a truncated polypeptide sequence of the hGGPPS protein sequence (SEQ ID NO:4) and wherein said contiguous span includes at least one amino acid selected from the group consisting of:

a. a Phe residue at position 204 of SEQ ID NO:4;

b. a Phe residue at position 295 of SEQ ID NO:4;

c. a~~A~~ Cys residue at position 205 of SEQ ID NO:4; and

d. a Pro residue at position 225 of SEQ ID NO:4.